

REMARKS

Claims 1-40 and 67 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards invention. The claims have been amended. Reconsideration and withdrawal of the rejection is requested.

Claims 4-6, and 9 stand objected to because of an improper preamble. The claims have been amended. Reconsideration is requested.

Claims 1-4, 9-12, 15-17, 20-22, 24-26, 28, 29, 51-57, 62, 63, 67, 102, and 103 stand rejected as understood, under 35 U.S.C. 102(b) as being anticipated by Rosenberg et al. (5,185,075). Rosenberg et al. (U.S. 5,185,075) is directed to surface treatment of titanium and titanium alloy articles. (Rosenberg, Title). Rosenberg discloses the production of a thin anodized film substantially of TiO₂ and characterized by the properties of leakage current, dielectric strength, breakdown potential and corrosion resistance. (Rosenberg, Abstract). The TiO₂ thin film is formed by anodizing the articles in a substantially non-aqueous solution of a mineral acid and an organic solvent. (Rosenberg, Abstract).

Independent claim 1, 51, 62 and 64 include, or have been amended to include, a limitation that the anodic treatment occurs in an “aqueous” solution (Claims 51, 53, 62 and 64) or a “substantially aqueous” solution (Claim 1). Because Rosenberg does not disclose these limitations, Applicant asserts that the rejection cannot stand. Dependent claims 2-4, 9-12, 15-17, 20-22, 24-26, 28-29, 52, 63, and 65-67 depend from one of these independent claims. Reconsideration and withdrawal of the rejection is requested.

Claims 53-54 have been canceled.

Independent claims 55, 56, 58, and 59 have been amended to include the limitation of “depositing hydroxyapatite over the anodically treated surface.” Rosenberg

does not disclose this limitation. Claims 57 and 60-61 depend from one of these independent claims. Reconsideration and withdrawal of the rejection is requested.

Claims 1, 3-5, 9-11, 15-22, 29, 51-55, 62-65, 67, and 102 stand rejected as understood, under 35 U.S.C. 102(b) as being anticipated by Haszmann et al. (5,354,390). Haszmann discloses a process for treating titanium or a titanium-base microalloy containing at least 98% by weight of titanium. (Haszmann, Abstract; col. 1, line 15; col. 3, lines 54-55). Anodic oxidation in an electrolyte forms an oxide layer with an amorphous structure. A heat treatment at 700 °C transforms the oxide layer to a crystalline structure. (Haszmann, col. 2, lines 33-45).

Independent claim 1 includes the limitation of treating a metal surface that includes “less than 98 percent titanium.” Haszmann does not disclose every limitation of the claim 1, as well as claims 3-5, 9-11, 15-22 and 29, which depend therefrom.

Independent claims 51, 62 and 64 have been amended to include the limitation of “the method not requiring temperatures greater than 65 degrees Celcius or pressures greater than one atmosphere to implement.” Haszmann does not disclose every limitation of claims 51, 62 and 64, as well as claims 52, 63, 65 and 67 which depend therefrom.

Claims 5 and 53-54 have been canceled.

Independent claim 55 has been amended to include the limitation of “depositing hydroxyapatite over the anodically treated surface.” Haszmann does not disclose this limitation. Claim 102 depends from claim 55.

Reconsideration and withdrawal of the rejection is requested.

Claims 53-61 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ishizawa (5,478,237). Ishizawa (U.S. 5,478,237) is discussed in the background of the present application, as follows:

U.S. Patent No. 5,478,237 (Ishizawa) provides an implant having a titanium or

titanium alloy surface having an anodic oxidation film formed on the surface, wherein the film contains calcium and phosphorus. The film is formed by anodic oxidation of the implant in an electrolyte containing between 0.1 and 0.5 molar concentration of a calcium compound and between 0.07 and 0.26 molar concentration of a phosphorus compound. A final hydrothermal treatment with steam is used to form a film of a calcium phosphate compound, such as hydroxyapatite, on the anodic oxide film. While a voltage range of 10 to 600 Volts is disclosed, the voltages in the examples are limited to the range of 300 to 390 Volts.

(Specification, para. [0011])

Claims 53-54 have been canceled.

Independent claims 55, 56, 58 and 59 have been amended to include the limitation of “depositing hydroxyapatite over the anodically treated surface.” Ishizawa does not disclose this limitation. Rather, Ishizawa uses a hydrothermal treatment under elevated pressure to transform the calcium and phosphorous containing compounds into hydroxyapatite. (Ishizawa, col. 6, lines 19-36). Claims 57 and 60-61 depend from one of these independent claims. Reconsideration and withdrawal of the rejection is requested.

Claims 13, 14, 18, 19, 23, and 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al. As previously discussed, Rosenberg does not teach, show or suggest the use of a substantially aqueous solution, as set out in amended claim 1. Claims 13, 14, 18, 19, 23 and 27 depend from claim 1. Reconsideration and withdrawal of the rejection is requested.

Claims 30-40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al. in view of Ishizawa. Claims 30-40 directly or indirectly depend from claim 1, which has been amended to include the limitation of “anodically treating at least a portion of a surface of the surgical implant or component that is disposed in a substantially calcium-free, substantially aqueous solution of a phosphorus-containing compound.”

The Applicant asserts that the Examiner's burden under 103 has not been met. As is well known, to establish a *prima facie* case of obviousness, three basic criteria must be met: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art reference must teach or suggest *all the claim limitations*. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F. 2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991).

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Rosenberg does not mention the use or presence of calcium in the anodic oxidation solutions, thereby leaving open the possibility that the solutions might be "substantially calcium-free." By contrast, Ishizawa discloses a method including placing the implant in an electrolyte solution containing a Ca-compound and a P-compound. (Ishizawa, col. 3, lines 52-56) to form an oxidation film containing Ca and P. (Ishizawa, col. 3, lines 41-47). Since Rosenberg and Ishizawa differ on the use of Ca, Applicant asserts that a combination of the references does not provide a clear suggestion of anodically treating the implant in a substantially calcium-free solution of a phosphorus-containing compound, as claimed.

The applicant asserts that the methods and structures of the invention as a whole

are quite different from Rosenberg and Ishizawa. Specifically, anodically treating with a Ca-free P-containing solution, is substantially different than anodically treating with a solution containing both Ca and P as taught by Ishizawa. The Applicant asserts that the references do not teach, show or suggest the invention as claimed.

The mandate of Section 103 is that the invention as a whole must be considered in obviousness determinations. “The invention as a whole embraces the structure, its properties, and the problem it solves.” *In re Wright*, 6 U.S.P.Q.2d 1959, 1963 (Fed. Cir. 1988). “In delineating the invention as a whole, we look not only to the subject matter which is literally recited in the claim in question . . . but also to those properties of the subject matter which are inherent in the subject matter and are disclosed in the specification.” *In re Antonie*, 195 U.S.P.Q. 6, 8 (CCPA 1977). The determination of whether a novel structure is or is not “obvious” requires cognizance of the properties of that structure and the problem which it solves, viewed in light of the teachings of the prior art. *In re Wright*, at 1963 (Referring to *In re Rinehart*, 189 U.S.P.Q. 143, 149 (CCPA 1976)). Reconsideration and withdrawal of the rejection is respectfully requested.

The Applicant also asserts that the Examiner has not established a motivation to combine Rosenberg and Ishizawa, as the office action includes no evidence in support of motivation. For prior art references to be combined to render obvious a subsequent invention under 35 U.S.C. Section 103, there must be something in the prior art as a whole which suggests the desirability, and thus the obviousness, of making the combination. *Uniroyal v. Rudkin-Wiley*, 5 U.S.P.Q.2d 1434, 1438 (Fed. Cir. 1988). The teachings of the references can be combined only if there is some suggestion or incentive in the prior art to do so. *In re Fine*, 5 U.S.P.Q.2d at 1599 (Fed. Cir. 1988). Hindsight is strictly forbidden. It is impermissible to use the claims as a framework from which to pick and choose among individual references to recreate the claimed invention. *Id.* at 1600; *W.L. Gore*, 220 U.S.P.Q. at 312. Moreover, the mere fact that a prior art structure could be modified to produce the claimed invention would not have made the modification obvious unless the prior art suggested the desirability of the modification.

In re Fritch, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992); *In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). Thus, a rejection under 35 U.S.C. Section 103 grounded on a combination of references cannot be sustained unless the particular combination is suggested by the prior art itself. The Applicant asserts that the prior art makes no suggestion to combine Rosenberg and Ishizawa and that the Examiner has not met the affirmative duty to show such a teaching in the art. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 6-8 and 66 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Haszmann et al. Claims 6-8 depend from independent claim 1 and claim 66 depends from independent claim 64. Therefore, Applicant asserts that these claims are allowable for at least the same reasons as the independent claims, discussed above. Reconsideration and withdrawal of the rejection is respectfully requested.

In the event there are additional charges in connection with the filing of this Response, the Commissioner is hereby authorized to charge the Deposit Account No. 50-0714/LYNN-0173.C of the firm of the below-signed attorney in the amount of any necessary fee.

Respectfully submitted,

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